

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

COUNCIL FOR RESPONSIBLE NUTRITION,

Plaintiff,

v.

LETITIA JAMES, in her official capacity as New
York Attorney General,

Defendant.

No. 24-cv-1881 (ALC)

**MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S
EMERGENCY MOTION FOR A PRELIMINARY INJUNCTION**

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PRELIMINARY STATEMENT

In October 2023, the New York State Legislature enacted A5610, the statute at issue in this action (the “Statute”), which restricts the sale to minors of certain dietary supplements used for weight loss and muscle building. By imposing an age-based sales restriction, the Legislature reasonably sought to reduce the unsupervised use by minors of these dietary supplements given the connection of such uses to eating disorders, and to raise general public awareness about the potential dangers of these widely available—and largely unregulated—products.

But now Plaintiff—a trade group representing dietary supplement manufacturers and distributors—seeks to invalidate the Statute on its face and prevent the Attorney General from enforcing it. This Court should deny Plaintiff’s motion for a preliminary injunction because Plaintiff cannot demonstrate it is entitled to the extraordinary remedy that it seeks.

Plaintiff fails to establish a likelihood of success on any of its claims. The Statute is a proper exercise of the State’s broad police powers to protect the public health and rationally seeks to address the growing prevalence of eating disorders by restricting the access of minors to weight loss and muscle building supplements, the use of which is associated with eating disorders and has resulted in other negative health outcomes. The Statute is not facially void for vagueness where its plain terms apply to a core of intentional conduct—namely, the selling to minors of dietary supplements which are labeled or marketed by the manufacturer or retailer for the purpose of achieving weight loss or muscle building. The Statute’s lack of vagueness is reinforced by its inclusion of detailed provisions guiding courts and state officials in enforcement. Questions about how the Statute may apply in hypothetical situations at the Statute’s periphery are not properly considered in a facial challenge—the only one before the Court here.

Plaintiff's First Amendment claim also fails because the Statute does not regulate commercial speech by prohibiting the sale of dietary supplements to minors. The voluntary decisions by Plaintiff's members to refrain from making certain claims about their dietary supplements for the purpose of evading the Statute's restrictions do not subject the Statute to First Amendment scrutiny. Even if the Statute is assumed to regulate commercial speech, it satisfies intermediate scrutiny because the Statute's age-based sales restriction directly and reasonably advances the State's substantial interest in protecting the public health. Plaintiff's criticisms of the Statute and its contention that other alternative means exist to address the State's valid interests are insufficient to defeat the reasonableness of the State's considered policy choice. And the Statute is not expressly preempted by federal laws governing labeling requirements because neither federal nor state law imposes any requirements for the labeling of dietary supplements that are relevant here, and thus there can be no conflict between the two.

Finally, Plaintiff cannot show that it is entitled to any relief, preliminary or otherwise. The declarations submitted by Plaintiff and its members only contain conclusory and speculative allegations of harm, and fail to establish the existence of any concrete and imminent injuries fairly traceable to the Statute as required by Article III. Nor can Plaintiff demonstrate irreparable harm based on it and its members' vague and unspecified assertions of injury, and Plaintiff's months-long delay in moving for preliminary relief undermines its claims of any immediate and irreparable harm. The equities weigh heavily against enjoining a duly-enacted state law, particularly one aimed at protecting minors and the general public health from potentially harmful weight loss and muscle building dietary supplements. On the other hand, granting the requested injunction would serve the interests of the multi-billion-dollar dietary supplement industry and permit the continued unregulated and unsupervised use (and misuse) of such supplements by children.

STATEMENT OF THE CASE

I. STATUTORY FRAMEWORK

Beginning in 2020, members of the Legislature sought to address the growing prevalence of the “serious public health problem” of eating disorders “affecting youth and adults of all races, ages, and genders.” Sponsor’s Mem. in Support for A10138 (2020), at 1; *accord* Sponsor’s Mem. in Support, in Bill Jacket for ch. 558 (2023), at 1-2. In particular, the sponsor of the bill observed that anorexia nervosa, the most common eating disorder, “has the 2nd highest mortality rate of all mental health conditions.” Sponsor’s Mem. in Support, in Bill Jacket for ch. 558 (2023), at 1-2. One chief concern for the Legislature was that an eating disorder is a mental health condition that may be identified and diagnosed based on “the presence of what clinicians call unhealthy weight control behaviors,” one of which is the use (or misuse) of dietary aids to promote weight loss or to build muscle. *See id.* Concerned that dietary supplements used for weight loss or muscle building were readily available “alongside multivitamins and other supplements largely regarded as safe,” the sponsor noted that there had been a number of reported instances of deaths and serious harms resulting from the largely unregulated use of dietary supplements. *Id.* Modeled after age restrictions for alcohol and tobacco, which “have been demonstrated to reduce . . . consumption” of those products by adolescents, the Legislature sought to implement an age restriction for the purchase of dietary supplements used for losing weight or building muscle, to reduce the unsupervised use of these products by minors and, more broadly, to “draw attention to the life-threatening risks that come along with these widely used products.” Sponsor’s Mem. in Supp. for A10138 (2020), at 2.

Following several rounds of revisions, on October 25, 2023, the Legislature enacted A5610, the subject of this action. Ch. 558, 2023 N.Y. Laws. Consistent with the original versions

of the law, the Statute provides that no person, company “or other entity shall sell or offer to sell or give away, as either a retail or wholesale promotion, . . . [a] dietary supplement for weight loss or muscle building within this state to any person under eighteen years of age.” Ch. 558, § 1, 2023 N.Y. Laws (to be codified at N.Y. Gen. Bus. Law § 391-oo(2)). As enacted, the Statute defines “dietary supplement for weight loss or muscle building” as “a class of dietary supplement as defined in section three hundred ninety-one-o of this article¹ that is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building.” Gen. Bus. Law § 391-oo(1)(a). Exempted from the age-based sales restriction are “protein powders, protein drinks and foods marketed as containing protein unless the protein powder, protein drink or food . . . contains an ingredient other than protein which would, considered alone, constitute a dietary supplement for weight loss or muscle building.” *Id.*

The Statute also contains a number of provisions clarifying its scope and guiding enforcement. In particular, the Statute clarifies that a supplement is “labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building” where its “labeling or marketing bears statements or images that express or imply that the product will help . . . modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the process by which nutrients are metabolized” or “maintain or increase muscle or strength.” *Id.* § 391-oo(6)(b)(i)-(ii). The Statute also directs courts, in enforcement proceedings, to consider whether a dietary supplement contains certain ingredients such as a steroid, or “creatine, green tea extract, raspberry ketone, garcinia cambogia, green coffee bean extract,” or “an ingredient approved by the federal Food and Drug Administration for weight loss or muscle building,” as the inclusion of

¹ “Dietary supplement” is defined, in relevant part, as an ingestible product that “contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid . . .” *See* Gen. Bus. Law § 831.

such ingredients commonly associated with weight loss or muscle building may bring a product within the Statute’s restrictions. *Id.* § 391-oo(6)(a)(i)-(iii). Further, the Statute provides that a dietary supplement may be subject to the age-based sales restriction through the actions of the retailer by “placing signs, categorizing, or tagging the supplement with statements” suggesting that the supplement will impact weight, fat, appetite, metabolism, muscle or strength, or by “grouping the supplements with other weight loss or muscle building products in a display, advertisement, webpage, or area of the store.” *Id.* § 391-oo(6)(d)(i)-(iii).

The Statute requires brick-and-mortar retailers who directly sell the covered products to the public to comply with the age-based sales restriction by requiring “proof of legal age” by means of a driver’s license or other types of identification at the point of sale. *Id.* § 391-oo(2). For online retailers, the Statute requires the retailer to use a method of mailing or shipping that requires proof that “the person who signs to accept delivery of the shipping container” is at least eighteen years of age. *Id.* § 391-oo(4)(b)(i)-(ii).

The Statute authorizes the Attorney General, in her discretion, to enforce violations of the Statute through special proceedings in state court. Upon notice to the alleged offender, and if a court finds a violation after considering the enumerated factors set forth in the Statute, the court may issue an injunction and impose a civil penalty of no more than \$500 per violation. *Id.* § 390-oo(5). The Statute takes effect on April 22, 2024. Ch. 558, § 2, 2023 N.Y. Laws.

II. PROCEDURAL HISTORY

On March 13, 2024, five months after the Statute was enacted, Plaintiff commenced this action, seeking a declaration that the Statute is facially invalid and an injunction barring the Attorney General from enforcing it. (ECF No. 1.) Three weeks later, on April 3, 2024, Plaintiff made an emergency motion for an order to show cause for a temporary restraining order and a

preliminary injunction, seeking immediate relief ahead of the Statute’s effective date. (ECF Nos. 14-25.) On April 4, 2024, the Court denied Plaintiff’s application for a temporary restraining order, directed the Attorney General to respond to Plaintiff’s motion by April 9, 2024, and set a hearing on Plaintiff’s motion for April 10, 2024. (ECF No. 31.)

STANDARD OF REVIEW

“A preliminary injunction is an extraordinary remedy never awarded as of right,” and requires “a clear showing” of all of the preliminary injunction factors: a likelihood of success on the merits; irreparable harm in the absence of preliminary relief; a balance of equities in the movant’s favor; and proof that an injunction would be in the public interest, *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20-24 (2008), with the latter two factors merging where, as here, the injunction would run against the government, *Nken v. Holder*, 556 U.S. 418, 435 (2009).

ARGUMENT

I. PLAINTIFF HAS NO LIKELIHOOD OF SUCCESS ON THE MERITS

A. The Statute Is a Proper Exercise of the State’s Police Powers.²

The Legislature possesses broad police powers to enact laws aimed at protecting public health and safety, *Lyn v. Inc. Vill. of Hempstead*, 308 F. App’x 461, 464 (2d Cir. 2009) (quoting *City of Erie v. Pap’s A.M.*, 529 U.S. 277, 296 (2000)), including that of its children, *Ginsberg v. State of N.Y.*, 390 U.S. 629, 639 (1968). As Plaintiff acknowledges (Pl.’s Br. at 26-27), challenges to a State’s exercise of its police powers are reviewed for reasonableness. *See, e.g., Jacobson v. Massachusetts*, 197 U.S. 11, 35 (1905).

² To the extent Plaintiff is bringing this claim based on the New York Constitution (Pl.’s Br. at 26 (citing state law)), it is barred by the Eleventh Amendment, regardless of the relief sought. *See Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 106 (1984).

Judicial review of a legislative action for reasonableness “is not a license for courts to judge the wisdom, fairness, or logic of legislative choices.” *Heller v. Doe*, 509 U.S. 312, 319 (1993) (citing *FCC v. Beach Commc’ns., Inc.*, 508 U.S. 307, 313 (1993)); *Jacobson*, 197 U.S. at 30 (“It is no part of the function of a court . . . to determine” which of the options the legislature had to deal with a problem “was likely to be the most effective for the protection of the public”). Under the “extremely deferential” rational basis review, laws bear “a strong presumption of validity,” and those attacking the rationality of the law “must discredit any conceivable basis which could be advanced to support the challenged provision, regardless of whether that basis has a foundation in the record, or actually motivated the legislature.” *United States v. Amalfi*, 47 F.4th 114, 124-25 (2d Cir. 2022). The Legislature is not required to “actually articulate at the time the purpose or rationale supporting” its actions, or to introduce evidence to justify its policy choices. *Heller*, 509 U.S. at 320. Courts “do not demand of legislatures ‘scientifically certain criteria of legislation.’” *Ginsberg*, 390 U.S. at 642-43. Nor are legislative actions “subject to courtroom fact-finding,” and may properly “be based on rational speculation unsupported by evidence or empirical data.” *Beach Commc’ns.*, 508 U.S. at 315. In short, a statute must be upheld as long as its rationality is “at least debatable.” *Amalfi*, 47 F.4th at 125.

The Statute easily satisfies rational basis review under these settled standards. Here, one of the articulated rationales for the Statute was to address the “serious public health problem” of eating disorders, which affects “youth and adults of all races, ages, and genders.” *See* Sponsor’s Mem. in Supp., in Bill Jacket for ch. 558 (2023), at 1-2. As noted in the sponsor’s memorandum, one of the behaviors associated with eating disorders is the use of dietary supplements aimed at weight loss or muscle building, which are readily accessible to minors and generally unregulated in the marketplace. *Id.* The Statute seeks to reduce the use of such supplements by minors by

“implementing an age-based restriction on sales” of these products, believing that the restrictions will also more generally “draw attention to the health risks of using these products.” *Id.*

It was plainly reasonable for the Legislature to restrict the ability of teenagers and children to buy dietary supplements identified as promoting weight loss or muscle building as a means of protecting the public health and raising awareness of the health risks attendant to the unfettered access of these substances by a vulnerable population. *See, e.g., Graham v. Florida*, 560 U.S. 48, 68 (2010) (recognizing that minors are differently situated than adults in that minors generally have a “lack of maturity” and are “more vulnerable or susceptible to negative influences and outside pressures”); *Ginsberg*, 390 U.S. at 636 (constitutionally permissible for State to restrict sales of dangerous materials to minors that are not restricted to adults). It cannot be seriously disputed that a restriction preventing minors from directly purchasing certain dietary supplements is a rational means of reducing the unsupervised use of those products by minors. Indeed, as the sponsor noted, laws imposing age-based restrictions on the sale of alcohol and tobacco were effective in reducing the consumption of those restricted items, *see* Sponsor’s Mem. in Support for A10138 (2020), at 2, an assertion that is well supported.³

Substantial research shows the increased prevalence of mental health conditions, including eating disorders, in recent years.⁴ Use or overuse of “diet aids” is known to be a potential indicator

³ *See* U.S. Federal Trade Commission, Consumer Advice, *21 Is the Legal Drinking Age* (data showing alcohol consumption by high school seniors falling from 66% to 42% since Congress enacted federal law setting 21 as the minimum age for purchasing alcohol), *available at* <https://consumer.ftc.gov/articles/0386-21-legal-drinking-age>.

⁴ *See, e.g.,* Centers for Disease Control & Prevention, *Pediatric Emergency Department Visits Associated with Mental Health Conditions Before and During the COVID-19 Pandemic—United States, Jan. 2019–Jan. 2022* (Feb. 25, 2022) (reporting substantial increase in emergency room visits for adolescent females for eating disorders and other mental health conditions), *available at* <https://tinyurl.com/yr2w6psm>; Carline Hopkins, NBC News, *Eating Disorders Among Teens More Severe than Ever* (Apr. 29, 2023), *available at* <https://tinyurl.com/rshkmep5>.

of an eating disorder.⁵ There exists ample support for the Legislature’s stated concerns about the risks to public health posed by the unchecked consumption of dietary supplements, and the connection between the use (and misuse) of dietary supplements and eating disorders and other negative public health outcomes.⁶ Anecdotal and other research-based evidence supports the Legislature’s view that curbing the use of certain dietary supplements by minors through age-based sales restrictions will protect the public health and raise general awareness of the health risks of the use of dietary supplements.⁷

Plaintiff cannot undermine the reasonableness of the Legislature’s determination merely by claiming that the restricted products are “safe,” or by proffering a study it funded and procured contending that dietary supplement use does not cause eating disorders. *See* Pl.’s Br. at 6, Compl.

⁵ *See, e.g.,* Mayo Clinic, Eating Disorders, Symptoms, *available at* <https://tinyurl.com/2f6psea2>; STRIPED letter to Legislature, dated April 2023 at 1, 5 (listing research connecting dietary supplement use with eating disorders and other health harms) (Ex. C to Declaration of Linda Fang (“Fang Decl.”)).

⁶ *See, e.g.,* Harvard T.H. Chan School of Public Health, STRIPED, “Dietary Supplements and Eating Disorders: Keeping Your Patients Safe” (discussing dietary supplement use and eating disorders), *available at* <https://tinyurl.com/mryepnyf>; Harvard T.H. Chan School of Public Health, *Dietary Supplements Linked with Severe Health Events in Children, Young Adults* (June 5, 2019), *available at* <https://tinyurl.com/3v32x2n3>; Deirdre McPhillips, CNN, *Nearly 1 in 10 Teens Worldwide Have Used Ineffective and Potentially Harmful Products, Study Estimates*, Jan. 10, 2024, *available at* <https://tinyurl.com/2m7hhdh8>; Natasha May, The Guardian, *Weight-Loss Products Should Not be Sold to Under-18s, Experts Warn* (Jan. 10, 2024), *available at* <https://tinyurl.com/2bhuj5bk>; Paula Cody, M.D., M.P.H., UW Health, *Dietary Supplements: Not Safe for Teens (or Anyone, Really)* (Aug. 23, 2017), *available at* <https://tinyurl.com/38t5bsfa>.

⁷ *See, e.g.,* Letter from Ryan A. to Governor Hochul, dated Aug. 16, 2022 (high school student reporting personal experiences related to dietary supplements and body dysmorphia in classmates) (Ex. D to Fang Decl.); Testimony from Jason M. Nagata, M.D., M.Sc., dated Apr. 26, 2021 (assistant professor of pediatrics attesting to scientific research documenting connection between dietary supplement use and eating disorders and other health harms) (Ex. E to Fang Decl.); Letter from Mark Oakley, Christine K. Briggs, and Pavel Hablyuk (former GNC employees and employee of dietary supplement company recounting experiences of being “often [] astonished by the number of adolescents as young as 12 to 17 years old, without their parents, looking for weight-loss and muscle building supplements in store” and inquiring about “the strongest supplement” available) (Ex. F to Fang Decl.).

¶ 76 & n.13. As the Supreme Court has explained, for purposes of rational basis review, which governs here, the fact that the belief which the Legislature acted upon “is not universal is not controlling, for there is scarcely any belief that is accepted by everyone.” *Jacobson*, 197 U.S. at 34-35 (legislature’s determination that vaccinations protect the public health is reasonable even where plaintiff submitted offers of proof from medical professionals stating that vaccination was ineffective in preventing spread of smallpox).

In this case, it is Plaintiff’s burden to conclusively refute “every conceivable basis which might support” the Statute—not the other way around. *Beach Commc’ns.*, 508 U.S. at 315. Plaintiff cannot do so. Accordingly, because the Statute was a proper exercise of the State’s broad powers in protecting the public health, Plaintiff has no likelihood of success on its *ultra vires* claim.

B. The Statute Is Not Unconstitutionally Vague on its Face.

Due process requires that laws “give the person of ordinary intelligence a reasonable opportunity to know what is prohibited” and “provide explicit standards for those who apply them.” *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). The void for vagueness doctrine “does not require meticulous specificity from every statute, as language is necessarily marked by a degree of imprecision.” *Thibodeau v. Portuondo*, 486 F.3d 61, 66 (2d Cir. 2007). A law is impermissibly vague not merely because it may “require[] a person to confirm his conduct to an imprecise but comprehensible normative standard, but rather in the sense that no standard of conduct is specified at all.” *Coates v. City of Cincinnati*, 402 U.S. 611, 614 (1971). To succeed on a facial challenge—the only one asserted here—the plaintiff “must demonstrate that the law is impermissibly vague in all of its applications.” *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497-98 (1982). Plaintiff cannot make this showing.

Here, under the Statute’s plain text, a dietary supplement comes within the sales restrictions

if the manufacturer’s packaging, statements, or marketing of the product identifies the supplement as aiding weight loss or muscle building by, for example, stating or suggesting that the product will “modify, maintain, or reduce body weight, fat, appetite, overall metabolism,” or will “maintain or increase muscle or strength.” Gen. Bus. Law § 391-oo(b)(i)-(ii). Retailers may also bring a dietary supplement within the scope of the sales restriction, irrespective of the labeling or marketing of the product itself by the manufacturer, by grouping a dietary supplement with other weight loss or muscle building supplements through in-store displays or online categorization of the products. *Id.* § 391-oo(d)(i)-(iii). The Statute also provides that dietary supplements may be subject to the sales restriction if they contain certain specifically enumerated ingredients, such as creatine or steroids, which are commonly associated with products marketed for weight loss or muscle building. Taken together, these terms are detailed and give businesses and individuals clear notice of the core of the regulated conduct.

Plaintiff’s own submissions confirm that the Statute sets forth clear and comprehensible standards. Notably, the declaration from a representative of XYMOGEN, one of Plaintiff’s members, demonstrates that XYMOGEN understands that the Statute’s proscriptions apply to at least a subset of its products. ECF No. 23 ¶¶ 13, 17 (attesting that XYMOGEN has identified a number of “impacted products and intends to either revise product labeling and marketing to remove applicable claims and/or to age-restrict impacted products,” and has “removed certain claims made in relation to six of [its] products”). And independent review of the websites associated with several of Plaintiff’s members reveals a number of products, which make express statements about suppressing appetite, enhancing weight loss, or boosting metabolism, or which group products under the category of “weight management.” *See* Ex. G to Fang Decl. Any reasonable person would understand that these products comfortably fit within the statutory

definition of a dietary supplement “labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building.” These clear cases, along with Plaintiff’s own members’ statements, foreclose the claim that the Statute provides “no standard of conduct” such that it is impermissibly vague in all of its applications. *See Vill. of Hoffman Estates*, 455 U.S. at 495 n.7.

The Supreme Court’s decision in the *Village of Hoffman Estates*, which concerned a facial challenge to a local regulation banning the sale of drug paraphernalia, confirms this conclusion. In that case, the Supreme Court rejected a facial challenge to a local law that made it unlawful for a person “to sell any items, effect, paraphernalia, accessory or thing which is designed or marketed for use with illegal cannabis or drugs.” 455 U.S. at 491-92. The court of appeals invalidated the law on its face because it found the law “vague with respect to certain conceivable applications.” *Id.* at 494. In reversing, the Supreme Court explained that the court of appeals’ holding was legally erroneous, because a statute is not vague on its face merely “because it is unclear in *some* of its applications to the conduct of [plaintiff] and of other hypothetical parties,” *Id.* at 495 (emphasis in original).

That some of Plaintiff’s members purportedly cannot identify whether certain of their products will be covered by the Statute likewise does not render the Statute facially invalid. *See id.* (“A plaintiff who engages in some conduct that is clearly proscribed cannot complain of the vagueness of the law as applied to the conduct of others.”). Such challenges must instead be considered on an as-applied basis, based on the challenger’s “actual conduct and not with respect to hypothetical situations at the periphery of the statute’s scope.” *VIP of Berlin, LLC v. Town of Berlin*, 593 F.3d 179, 189 (2d Cir. 2010) (for as-applied vagueness claims, courts must focus on plaintiff’s actual conduct and not “whether a reasonable person would understand that certain hypothetical conduct or situations violate the statute”). A facial challenge is not the appropriate

forum to engage in speculation about a range of hypothetical circumstances. *See Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450 (2008) (facial challenges are “disfavored” because they “often rest on speculation” and “raise the risk of premature interpretation of statutes on the basis of factually barebones records”).

Because the Statute’s proscriptions apply with clarity to at least a subset of Plaintiff’s members’ circumstances, Plaintiff’s facial challenge to the Statute must be rejected, and this Court need not proceed further. But even considering Plaintiff’s other due process arguments, none are sufficient to establish that Plaintiff’s facial challenge to the Statute is likely to succeed.

In contending that the Statute is unconstitutionally vague, Plaintiff raises a number of unavailing arguments. Plaintiff contends that the phrase “labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building” is impermissibly vague. While not specifically disputing that “labeled” and “marketed” are properly understood to refer to a manufacturer or seller’s actions, Plaintiff nonetheless insists that the Statute must be struck on its face because the Statute does not define what “represented” means, and because that term “could, in theory, apply to any statement made by anyone, anywhere—including in the endless abyss of the internet—and it could apply regardless of whether the statement was authorized by the company facing liability, the intent of the speaker, or whether the statement was heard or read by a minor in New York.” *See* Pl.’s Br. at 7, 14. But Plaintiff cannot invalidate a state law in *all* of its applications merely by advancing its own unsupported views about how the statute could conceivably apply in *some* hypothetical situations.

Notably, in considering an analogous law in *Village of Hoffman Estates*, the Supreme Court held that the term “marketed for” refers to “a retailer’s intentional display and marketing of merchandise,” and the term’s inclusion did not render the law unconstitutionally vague. 455 U.S.

at 499-503 (ordinary understanding of the term “designed and marketed for use” “requires scienter, since a retailer could scarcely ‘market’ items ‘for’ a particular use without intending that use”). Applied here, the Statute’s use of “labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building” is most naturally understood to refer to the labeling, marketing, and other representations about the product made by the manufacturer or seller. *See Orinoco Realty Co. Bandler*, 233 N.Y. 24, 30 (1922) (legislatures presumed to have knowledge of judicial interpretations of statutory terms).

Contrary to Plaintiff’s contention (Pl.’s Br. at 14), there is no basis for construing “represented” to apply to third party actions or statements. Under settled doctrines of statutory construction, courts must interpret a term in light of its surrounding text, to “avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth” to legislative acts. *Yates v. United States*, 574 U.S. 528, 543 (2015) (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995)). Here, the term “represented” directly follows “labeled” and “marketed,” which, consistent with Supreme Court precedent, refer to the intentional actions by the retailer or seller of the product. *See Vill. of Hoffman Estates*, 455 U.S. at 502-03. Thus, a straightforward interpretation of “represented” likewise refers to representations made by the retailer or seller, as opposed to potential representations made by others unbeknownst to the seller subject to the sales restriction. Construing “represented” this way—as imposing a scienter requirement on the part of the party with the potential liability—further undermines any claims of vagueness. *See, e.g., Vill. of Hoffman Estates*, 455 U.S. at 499 (“a scienter requirement may mitigate a law’s vagueness”); *United States v. Posters N Things Ltd.*, 969 F.2d 652, 660 (8th Cir. 1992) (statute’s “clear core of prohibited conduct” combined with scienter element “defeats a facial vagueness attack”); *United States v. Shvartsman*, No. 23-cr-307 (LJL), 2024 WL 1193703,

at *11 (S.D.N.Y. Mar. 20, 2024) (same). Even assuming there is ambiguity as to the meaning of “represented,” basic canons of statutory construction counsel in favor of construing the term to avoid constitutional problems. *See, e.g., 1256 Hertel Ave. Assocs., LLC v. Calloway*, 761 F.3d 252, 260-61 (2d Cir. 2014); *see also Kolender v. Lawson*, 461 U.S. 352, 355 (1983) (“In evaluating a facial challenge to a state law, a federal court must, of course, consider any limiting construction that a state court or enforcement agency has proffered.”).

Plaintiff is also mistaken when it contends that that the Statute must be invalidated on its face merely because the Statute directs courts to consider a non-exhaustive list of factors in determining whether a product is covered by the sales restriction. *See Posters N Things Ltd.*, 969 F.2d at 655-56 (statute providing that courts should consider list of enumerated criteria “in addition to all other logically relevant factors” not void for vagueness); *Levas & Levas v. Vill. of Antioch*, 684 F.2d 446, 454 (7th Cir. 1982) (law’s use of “non-exhaustive list of factors that a court or other authority should consider” did not render it vague). And the Statute is not impermissibly vague simply because it fails to define terms, since courts (and regulated parties) are presumed to be capable of understanding the words used in a statute by referring to their ordinary dictionary definitions. *See People v. Aleynikov*, 31 N.Y.3d 383, 397 (2018) (“When a word used in a statute is not defined in the statute, dictionary definitions serve as useful guideposts.”).

At bottom, Plaintiff’s speculation about how the Statute may apply in hypothetical cases is insufficient to render the Statute facially invalid. As the Second Circuit has explained, laws “are not impermissibly vague simply because it may be too difficult to determine whether marginal cases fall within their scope.” *United States v. Sun & Sand Imports, Ltd., Inc.*, 725 F.2d 184, 187 (2d Cir. 1984). Nor can “a finding of unconstitutional vagueness . . . be based on . . . a parade of bizarre hypothetical cases: problems of that order can be resolved in challenges to the [law] as

applied.” *Levas & Levas*, 684 F.2d at 451. Indeed, that judges may reasonably disagree about whether a statute applies in any given case does not render a statutory proscription unconstitutionally “shapeless” for due process purposes because “even clear rules produce close cases.” *Salman v. United States*, 580 U.S. 39, 51 (2016).

C. The Statute Does Not Violate the First Amendment.

1. The plain text of the Statute regulates conduct, not speech.

Plaintiff’s First Amendment claim flows from the fundamentally flawed premise that the Statute “restricts protected commercial speech,” and “suppress[es] truthful information” about dietary supplements. *See* Pl.’s Br. at 17, 19. But nothing in the text of the Statute regulates the content of Plaintiff’s members’ labeling or marketing of their products, or compels them to engage in—or refrain from—any particular speech. No provision of the Statute bans or regulates any advertising or marketing related to any products that Plaintiff’s members manufacture or sell. Instead, the Statute is directed solely towards conduct: namely, restricting the sale of certain dietary supplements to a particular class of consumers. Both before and after the Statute takes effect, Plaintiff’s members are free to label or market their products as promoting weight loss or muscle building, consistent with their business objectives to maximize sales and profit.

Regulations like the Statute which are directed at sales practices do not violate the First Amendment even if they may incidentally touch on “conduct that may have a communicative component.” *See, e.g., Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569-70 (2001) (display regulation); *Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 76-77 (1st Cir. 2013) (pricing discounts). A law that “neither limits what [a plaintiff] may say nor requires

them to say anything . . . regulates conduct, not speech.”⁸ See *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.*, 547 U.S. 47, 60 (2006) (federal law requiring schools to allow military recruiters equal access does not regulate speech even if schools must engage in certain speech to ensure equal access); *Slattery v. Hochul*, 61 F.4th 278, 291 (2d Cir. 2023) (prohibition against personnel actions not speech regulation even if it may affect employers’ ability to “advocate its views”).

For example, in *Village of Hoffman Estates*, the Supreme Court held that a local ordinance prohibiting the sale of certain items “designed or marketed for use” with drugs did not infringe the First Amendment rights of the retailer, but “simply regulate[d] business behavior.” 455 U.S. 489, 492-93, 495-99. Similarly, in *Lorillard Tobacco*, the Supreme Court rejected a First Amendment challenge to a state law that made it more difficult for buyers to purchase cigarettes and cigars—by prohibiting self-service displays for cigarettes and cigars, thereby necessitating buyers to have “direct contact with a sales person” and undergo the required age verification—based on the court’s conclusion that the primary purpose of the law was to regulate conduct “unrelated to the communication of ideas.” 533 U.S. at 569; see also *Art & Antique Dealers League of Am., Inc. v. Seggos*, 523 F. Supp. 3d 641, 646 (S.D.N.Y. 2021) (prohibition against displaying certain products is an “ordinary economic regulation of commercial activity” and imposes only “an incidental burden on speech”). And the First Circuit likewise rejected a claim that a state law “designed to discourage consumption” of tobacco by prohibiting retailers from discounting tobacco products violated the First Amendment on the grounds, among other things, that the regulation was directed at conduct, not speech. See *Nat’l Ass’n of Tobacco Outlets*, 731 F.3d at 76-77. Like the laws upheld

⁸ The First Amendment also protects against the government’s regulation of certain “expressive services,” but Plaintiff has not alleged that the sale of dietary supplements concerns anything more than commercial transactions involving “ordinary, non-expressive goods and services,” which do not implicate the First Amendment. See *303 Creative LLC v. Elenis*, 600 U.S. 570, 599 & n.6 (2023).

in these cases, the Statute is directed to regulating conduct, does not restrict Plaintiff's or its members' ability to communicate about their products to consumers, and thus does not violate the First Amendment.

Plaintiff's insistence that the Statute regulates commercial speech appears to stem from its view, and that of its members, that manufacturers and retailers may choose to change their labeling or marketing as a means of evading the sales restrictions imposed by the Statute. *See, e.g.*, ECF No. 23 ¶ 17 (XYMOGEN representative claiming that company has decided to "remove certain claims made in relation to six of our products"); ECF No. 22 ¶ 15 (suggesting that Pharmavite may alter "both the marketing and sale of dietary supplements" in light of the Statute). But these voluntary business decisions on the part of individual companies to alter their speech in response to the Statute's sales restriction does not render the Statute itself a speech restriction. It cannot be seriously contended that the Statute "*discourages* disclosure of information to the consumer" as Plaintiff claims (Pl.'s Br. at 20 (emphasis in original)), when the only reason manufacturers and retailers would withhold any information would be for purposes of circumventing the Statute's proscriptions so that they can continue selling their products to minors.

It is plain from the legislative history of the Statute that the Legislature's focus was always on restricting the sale of certain products—dietary supplements used for weight loss or muscle building—as opposed to targeting any disfavored message. Nor has Plaintiff claimed to the contrary. *See* Pl.'s Br. at 24 (asserting "the State *did not appreciate*" the extent of the purported burdens on speech "before passing" the Statute) (emphasis added). That the Statute relies on how manufacturers and retailers describe their own products, among other things, to determine which products are subject to the sales restrictions does not transform the law into a speech regulation. *See Lorillard Tobacco Co. v. Reilly*, 84 F. Supp. 2d 180, 195-96 (D. Mass. 2000) (information

concerning the “characteristics of the commodity” offered for sale does not implicate protected speech).

2. Even if the Statute regulates commercial speech, it satisfies intermediate scrutiny.

Because the Statute does not regulate speech to begin with, Plaintiff cannot state a First Amendment claim as a matter of law. But even assuming that the Statute can be regarded as a commercial speech regulation, Plaintiff cannot show that its First Amendment claim is likely to succeed.⁹ Among the types of speech protected under the First Amendment, commercial speech is “more hardy, and less likely to be ‘chilled,’ *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 481 (1989), as it is “the offspring of economic self-interest,” *Central Hudson Gas & Elec. Corp. v. Public Svcs. Comm.*, 447 U.S. 557, 564 n.6 (1980). To determine whether a regulation of commercial speech is constitutionally permissible, courts must determine whether (1) the speech concerns lawful activity and is otherwise protected by the First Amendment, (2) the asserted governmental interest is substantial, (3) the regulation directly advances the asserted government interest; and (4) the regulation is no more extensive than necessary to serve that interest. *Central Hudson*, 447 U.S. at 566.

Although the Attorney General disputes that the First Amendment is implicated at all by the Statute, assuming that the Court concludes otherwise, the first prong of the *Central Hudson* test would be satisfied, and only the second, third and fourth *Central Hudson* prongs are at issue. Here, the government interest underlying the Statute is the State’s stated interest in promoting the public health—more specifically, in reducing the incidence of the use of dietary supplements for weight loss and muscle building by minors, and promoting awareness of the potential dangers of

⁹ Plaintiff does not allege that the Statute seeks to regulate anything other than commercial speech, or that a stricter standard than intermediate scrutiny should apply. *See* Pl.’s Br. at 17-26.

the unregulated consumption of such dietary supplements more generally. *See* Sponsor’s Mem. in Support, at 4-5. Courts have uniformly recognized such interests to be substantial. *See, e.g., Lorillard Tobacco*, 533 U.S. at 569 (state has “substantial interest in preventing access to tobacco products by minors”); *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 275 (2d Cir. 2010) (state has substantial interest in protecting public health); *USA Baseball v. City of N.Y.*, 509 F. Supp. 2d 285, 303 (S.D.N.Y. 2007) (“The protection of the health and safety of high school age students is entitled to great weight”). Plaintiff does not dispute this uncontroversial proposition, *see* Pl.’s Br. at 19,¹⁰ and thus the second prong of the *Central Hudson* analysis is met.

The last two prongs of the *Central Hudson* test seek to ensure a “fit” between the government’s stated interest and “the means chosen to accomplish those ends.” *Fox*, 492 U.S. at 480. To pass constitutional muster, the “fit” does not need to be “perfect,” but merely “reasonable,” and does not need to be “the single best disposition” or “the least restrictive means.” *Id.*

There can be no dispute here that the public health problems sought to be addressed by the Statute—the prevalence of eating disorders, and the health harms from the unregulated use of dietary supplements used for weight loss and muscle building—are real. *See* Pl.’s Br. at 21 (acknowledging eating disorders are “unquestionably a real harm”). The legislative record and widespread reports confirm the existence of these threats to the public health. *See supra* at 8-9 & nn. 4-7. The State’s “accumulated, commonsense judgment” about the existence of these harms is entitled to deference. *See Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 509 (1981).

The third *Central Hudson* prong is satisfied because the Statute directly and materially

¹⁰ For purposes of the *Central Hudson* analysis, it is the government’s stated interests, as set forth in the law itself or as evident from the legislative history, that control—not the interest Plaintiff subjectively attributes to the Statute. *See* Pl.’s Br. at 19-20 (acknowledging that the State’s interests in protecting public health are “substantial” but arguing the States lacks “any interest in depriving citizens of truthful information relevant to their health”).

advances the State’s interests in addressing these harms. There is ample evidence in the legislative record and the public health discourse that the use of dietary supplements for weight loss and muscle building is a behavior that is associated with eating disorders. *See supra* at 8-9 & nn. 5-7. And empirical evidence has demonstrated that imposing age-based restrictions of products is effective in meaningfully reducing the access to those restricted products by minors. *See supra* at 8 n.3; *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (suggesting that purchasing restrictions are likely to be a more direct means of achieving the state’s goal of reducing alcohol consumption than banning certain types of price advertising). And, as a matter of common sense, imposing an age-based restriction on product sales, which requires proof of legal age at the point of sale or delivery, is likely to raise general public awareness about the products subject to the restrictions and their safety.

In urging the Court to second-guess the Legislature’s judgment, Plaintiff contends that the Statute does not meaningfully advance the State’s interests in protecting the public health because the Legislature failed to “demand[] to see the ‘body of research’” concerning eating disorders and dietary supplements referred to by the Statute’s sponsor. *See* Pl.’s Br. at 22. But “New York is not required to produce ‘empirical data . . . accompanied by a surfeit of background information’ in order to satisfy intermediate scrutiny. *Art & Antique Dealers*, 523 F. Supp. 3d at 647 (quoting *Lorillard Tobacco Co.*, 533 U.S. at 555). As the Supreme Court has recognized, state laws may be justified “by reference to studies and anecdotes . . . or even . . . based solely on history, consensus, and ‘simple common sense.’” *Lorillard Tobacco*, 533 U.S. at 555 (quoting *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 628 (1995)). The Statute easily passes constitutional muster on these bases, as there exists ample scientific and anecdotal evidence supporting a connection between the sales restriction imposed by the Statute and the public health interests it seeks to advance. *See*

supra at 8-9 nn. 4-7.

Nor is Plaintiff correct in contending that the Statute fails to satisfy the “reasonable fit” test because the sales restrictions are overinclusive and underinclusive. *See* Pl.’s Br. at 23 (criticizing the Statute’s “potential loopholes” and its failure to restrict sales of laxatives and diuretics). That the Statute is not the perfect means of achieving the State’s interests in reducing the use of unregulated dietary supplements by minors does not render it constitutionally infirm. *See, e.g., Vugo, Inc. v. City of N.Y.*, 931 F.3d 42, 52-53 (2d Cir. 2019) (city’s in-ride advertising ban for taxis materially advances the city’s interest in reducing passenger annoyance despite exceptions). Where, as here, the challenged law is a logical and effective means of addressing a valid and substantial government interest, it does not fail the “fit” prong of the *Central Hudson* test merely because the Statute does not solve the entirety of the perceived problem. “The government is not required to ‘make progress on every front before it can make progress on any front.’” *Vugo*, 931 F.3d at 54; *City of New Orleans v. Duke*, 427 U.S. 297, 303 (1976) (“Legislatures may implement their program step by step, in such economic areas, adopting regulations that only partially ameliorate a perceived evil and deferring complete elimination of the evil to future regulations.”).

Finally, the Statute satisfies the fourth *Central Hudson* requirement: the Statute does not “burden substantially more speech than is necessary” in advancing the State’s interests in protecting the public health and addressing the prevalence of eating disorders. *See Vugo*, 931 F.3d at 58. Again, as explained *supra*, the Statute does not directly burden or impact speech at all. It was plainly not the intent of the Legislature that Plaintiff’s members will opt to refrain from certain marketing or labeling practices to evade the Statute’s sales restrictions. Rather, the Legislature merely sought to prevent minors from having unfettered access to dietary supplements for weight loss or muscle building through the imposition of a sales restriction. The Statute does not directly

restrict marketing or labeling related to weight loss or muscle building, or mandate any disclosures. Nor does the Statute generally deprive consumers—minors and adults alike—of the ability to obtain dietary supplements, including those regulated by the Statute: nothing in the Statute prevents parents from purchasing dietary supplements for their children, or prevents adults from purchasing dietary supplements, regardless of their labeling or marketing.

In arguing that the Statute impermissibly burdens commercial speech, Plaintiff misplaces its reliance on the fact that an earlier version of the Statute “did not involve speech,” and on its contention that the State could have achieved its public health interests in conducting its own educational campaign about the dangers of unregulated dietary supplements. *See* Pl.’s Br. at 25-26. But the fourth prong of the *Central Hudson* analysis “does not require that there be no conceivable alternative to the government’s approach, or that the government’s regulation be the least restrictive means of advancing its asserted interests.” *Vugo*, 931 F.3d at 58 (quoting *Fox*, 492 U.S. at 478). That the Legislature could have addressed the State’s legitimate interests through other means does not mean that its chosen means are invalid.

Here, the Legislature made the reasonable decision to address the public health concerns it perceived by imposing an age-based restriction on the sale of certain dietary supplements, based on its belief that the restriction would reduce the use of such supplements by minors and generally raise public awareness about the safety concerns surrounding the dietary supplement market. The Court should not “second-guess” the measured policy judgment of the Legislature in this regard. *See Vugo*, 931 F.3d at 58 (government should be “afforded considerable leeway in determining the appropriate means to further a legitimate government interest”).

D. The Statute is Not Preempted by Federal Law.

The sole source of Plaintiff’s preemption claim (Pl.’s Br. at 28) is 21 U.S.C. § 343-1(a),

which expressly preempts any state “requirement respecting any claim [about nutritional levels and health benefits] . . . made in the label or labeling of food that is not identical to the requirement of [21 U.S.C.] § 343(r).” 21 U.S.C. § 343-1(a). Section 343(r), in turn, governs voluntary claims about health-related benefits that dietary supplement manufacturers are permitted to make about their products. *Id.* § 343(r)(1)(B) (statements describing “the relationship of any nutrient . . . to a disease or health-related condition”), (r)(6) (providing that dietary supplement labels *may* make certain claims about the health-related benefits provided manufacturer has “substantiation that such statement is truthful and not misleading,” among other things); *see generally Kaufman v. CVS Caremark Corp.*, 836 F.3d 88, 91-93 (1st Cir. 2016) (discussing statutory framework of §§ 343-1(a) and 343(r) and CVS’s statement that Vitamin E “supports heart health” in context of preemption of state law fraud claim).

The plain text of the federal statutes relied on by Plaintiff forecloses Plaintiff’s express preemption claim. Neither federal nor state law imposes any “requirement” as to what health-related statements Plaintiff’s members must make on their labeling. *See* 21 U.S.C. § 343-1(a). Indeed, the Statute in no way prohibits or otherwise restricts the ability of Plaintiff or its members to make any statements concerning the purported health-related benefits of a dietary supplement that they are permitted to make under federal law. That Plaintiff’s members may *choose* to refrain from making health-related claims as a means of avoiding the Statute’s age-based sales restrictions does not transform the Statute’s sales restriction into a labeling requirement. There is thus simply no basis for express preemption here. *See also N.Y. State Rest. Ass’n v. N.Y. City Bd. of Health*, 556 F.3d 114, 123-31 (2d Cir. 2009) (ordinance requiring restaurants to disclose calorie counts not preempted by federal law governing nutritional content labeling); *Grocery Mfrs. Ass’n v. Sorell*, 102 F. Supp. 3d 583, 612-15 (D. Vt. 2015) (state law that did not require changes to existing

labeling required by federal law not preempted).

There is likewise no basis for conflict preemption. Here, it is not “physically impossible” to comply with the age-based sales restrictions imposed by the Statute and the standards governing the voluntary health-related claims set forth in federal law. *See, e.g., Mutual Pharms. Co. v. Bartlett*, 570 U.S. 472, 503 (2013). Nor does the Statute’s restrictions on sales of certain dietary supplements pose “an obstacle to the accomplishment and execution of the full purposes and objectives of” federal law, *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), which requires that health-related claims, if they are made, to be substantiated and not misleading, 21 U.S.C. § 343(r)(6).

II. PLAINTIFF IS NOT ENTITLED TO THE PRELIMINARY RELIEF IT SEEKS

In addition to being unable to demonstrate a likelihood of success on the merits, Plaintiff’s motion fails because it cannot satisfy the irreparable harm and equities requirements warranting the grant of the “extraordinary relief” of a preliminary injunction. *Winter*, 555 U.S. at 22. And more fundamentally, Plaintiff fails to demonstrate that it has Article III standing.

A. Plaintiff Fails to Demonstrate Concrete and Imminent Injuries Fairly Traceable to the Statute.

In cases brought by an associational litigant, the plaintiff must show, among other things, that its members would otherwise have standing to sue in their own right. *See Hunt v. Wash. State Apple Advertising Comm’n.*, 432 U.S. 333, 341–44 (1977). Here, Plaintiff and its members assert three types of injuries arising from the Statute: (1) threat of enforcement; (2) impairment of free speech rights; and (3) economic losses. None are sufficiently demonstrated here, especially at the preliminary injunction stage, where Plaintiff’s burden is heightened. *See, e.g., Cacchillo v. Insmmed, Inc.*, 638 F.3d 401, 404 (2d Cir. 2011) (plaintiff’s burden is “no less than that required on a motion for summary judgment”; plaintiff must set forth concrete evidence of “specific facts”).

Plaintiff’s submissions fail to establish that its members have any concrete “intention to

engage in a course of conduct” prohibited by law, *Vitagliano v. County of Westchester*, 71 F.4th 130, 137-38 (2d Cir. 2023), that would subject them to a “credible threat” of enforcement, *Cayuga Nation v. Tanner*, 824 F.3d 321, 331-32 (2d Cir. 2016). As an initial matter, although a number of Plaintiff’s members’ declarations articulate general fears of reputational and other harms arising from threatened enforcement by the Attorney General, it bears emphasis that the Statute’s proscriptions only apply to persons or entities who sell the covered products directly to consumers. *See* Gen. Bus. Law § 391-oo(2). The Statute does not apply to manufacturers or distributors who merely provide the covered products to retailers or wholesalers, so long as they do not otherwise transact with consumers directly. Of the nine declarations submitted by Plaintiff’s members, only four are from companies that directly sell products to consumers (*see* ECF Nos. 19, 22-24)—the rest are from companies that merely produce or manufacture dietary supplements (*see* ECF Nos. 16-18, 20-21). The latter companies do not face any possibility of enforcement under the Statute because they do not sell any dietary supplements directly to consumers.

Even as to Plaintiff’s seller members, their declarations fail to demonstrate, with any specificity, that they have “concrete plans to perform, in the near future, the conduct that officials would consider illegal.” *See Kearns v. Cuomo*, 415 F. Supp. 3d 319, 330 (W.D.N.Y. 2019) (claim of threatened prosecution by federal authorities based on compliance with state law speculative where plaintiff did not allege whether he intended to comply with the state law to begin with) (quoting *Jones v. Schneiderman*, 101 F. Supp. 3d 283, 291 (S.D.N.Y. 2015)). A number of the declarations here aver that the companies purportedly have to choose between “facing the risk of an enforcement action” or “overwhelmingly erring on the side of caution with respect to both the marketing and sale of dietary supplements.” *E.g.*, ECF Nos. 19 ¶ 15, 22 ¶ 18, 24 ¶ 17. But the declarations do not provide any specifics as to which products these claims pertain or how the

companies are contemplating changing their marketing and sales practices. Nor do the seller members' declarations identify a single product that they intend to continue selling, subject to the Statute's age restrictions, or any product the continued sale of which they believe may expose them to enforcement under the Statute, or provide details about their actual labeling and marketing for any products. The absence of such factual specifics makes it impossible for the Court to determine whether the seller members' alleged fears of enforcement are sufficiently plausible and credible, or merely wholly imagined or speculative. While a plaintiff is not required to "confess that [it] will in fact violate the law," in this case the declarations submitted by the seller members fail to set forth any specific intentions for conduct from which the Court may make an objective determination on standing. *See Picard v. Magliano*, 42 F.4th 89, 98 (2d Cir. 2022).

As to the First Amendment claim, the declarations from Plaintiff's members likewise fail to establish standing. As explained *supra*, the Statute does not directly restrict speech, and the voluntary decisions of Plaintiff and its members to alter or withhold certain of their speech concerning some of the products they sell does not give rise to a cognizable injury that is fairly traceable to the Statute. *See, e.g., Clapper v. Amnesty Int'l. USA*, 568 U.S. 398, 418 (2013) (self-inflicted injuries based on subjective fears insufficient for standing); *Chrysafis v. Marks*, 573 F. Supp. 3d 831, 847 (E.D.N.Y. 2021) ("Self-inflicted injury that results from a plaintiff's personal choices" does not confer standing to sue). Some of the declarations here contain conclusory claims that the Statute will "substantially chill" commercial speech, but provide no specifics as to what messages or statements are at issue, or why they would be chilled. *E.g.*, ECF No. 22 ¶ 18. It is likewise unclear from the declarations, especially the ones from the companies that describe themselves as "contract manufacturers" (*e.g.*, ECF Nos. 18 ¶ 4, 20 ¶ 4, 21 ¶ 4), that these companies engage in any labeling or marketing of dietary supplements to begin with such that they

have any relevant speech that may be chilled at all. Nor do such manufacturer members have standing to assert the speech interests of their customers, as a general matter. *E.g.*, ECF No. 21 ¶ 12 (stating that Vitaquest’s *customers* must change their labeling).

Finally, the declarations are also uniformly lacking in specific details and facts and thus fail to demonstrate that the claims of potential economic losses—in terms of loss of customers or revenue—are actual or “sufficiently imminent” to support standing. *See Lacewell v. Office of Comptroller of Currency*, 999 F.3d 130, 146-47 (2d Cir. 2021) (allegations of anticipated loss of future revenue resulting from regulatory action were speculative where plaintiff did not demonstrate loss of revenue was “inevitable” or sufficiently likely). Many of the declarants generalize “reasonably anticipat[ing] that one or more of [their] customers would reduce orders . . . or could exit the market,” and hypothesize about the purported harms that may occur “if customers of other manufacturers reduce distribution or exit the market” (*e.g.*, ECF Nos. 18 ¶¶ 11-13, 20 ¶¶ 13-15) (emphasis added), but they altogether fail to assert—even though the Statute is within days of taking effect—that any customer has actually been lost, any orders have actually been reduced, or provide any concrete specifics to support their conclusory claims of future losses. *See Parker Madison Partners v. Airbnb, Inc.*, 283 F. Supp. 3d 174, 181 (S.D.N.Y. 2017) (plaintiff’s claims of “damage to their business, including but not limited to substantial lost business,” without specifics about “any current or potential clients that have been lost,” too conclusory to confer standing).

B. Plaintiff Cannot Demonstrate Irreparable Harm Absent an Injunction or that the Equities Weigh in Its Favor.

Plaintiff posits two forms of injury that it claims are irreparable: the alleged impairment of its First Amendment rights, and the claimed economic costs of complying with the Statute and those resulting from the Statute’s restrictions. *See* Pl.’s Br. at 32-33. In this case, contrary to

Plaintiff's claim (Pl.'s Br. at 32), Plaintiff is not entitled to a presumption of irreparable harm to its First Amendment rights where, as here, the challenged law does not "directly limit[] speech." *Bronx Household of Faith v. Bd. of Ed. of the City of N.Y.*, 331 F.3d 342, 349 (2d Cir. 2003). Rather, where "a plaintiff alleges injury from a rule or regulation that may only potentially affect speech, it must articulate a specific present object harm or a threat of specific future harm." *Citizens United v. Schneiderman*, 115 F. Supp. 3d 457, 473 (S.D.N.Y. 2015) (quoting *Bronx Household*, 331 F.3d at 350). Plaintiff cannot do so, because the Statute does not restrict speech, and Plaintiff and its members' self-inflicted injuries in seeking to avoid application of the Statute's restrictions do not give rise to a cognizable harm. *See supra* at 16-18, 27.

Plaintiff's claims of economic injuries are likewise insufficient. The Second Circuit has held that "ordinary compliance costs" of complying with government regulation is "typically insufficient to constitute irreparable harm." *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005) (collecting cases). And, as detailed *supra*, Plaintiff's claims of injury predicated on the loss of future revenue and customers are too conclusory and speculative to satisfy Article III.

Moreover, Plaintiff's substantial delay in moving for preliminary relief further undermines its claims of immediate, irreparable harm. The Statute was enacted in October 2023. Yet Plaintiff waited five months before bringing this action, and another three weeks to move for "emergency" relief. (ECF Nos. 1, 14.) Any emergency here was one of Plaintiff's own making, in waiting until the eve of the Statute's effective date, after having already purportedly incurred compliance costs that Plaintiff and its members claim are unrecoverable, before seeking preliminary relief. Plaintiff's delay undermines any claim of irreparable harm. *See, e.g., Tough Traveler, Ltd. v. Outbound Prod.*, 60 F.3d 964, 968 (2d Cir. 1995) (months-long delay in bringing suit and moving for preliminary injunction negates presumption of irreparable harm); *Citibank N.A. v. Citytrust*,

756 F.2d 273, 276-77 (2d Cir. 1985) (affirming denial of preliminary injunction where plaintiff waited ten weeks after learning of facts giving rise to claims to seek injunction).

Finally, the equities and public interest counsel strongly against a preliminary injunction. *See N.Y. State Rest. Ass’n v. N.Y. City Bd. of Health*, 545 F. Supp. 2d 363, 368 (S.D.N.Y. 2008) (“The public interest . . . in enforcement of legislation enacted in the public interest, weigh[s] heavily against granting a stay of enforcement.”). Enjoining the Statute, which seeks to protect minors from the associated physical and mental health harms of the use of dietary supplements for weight loss and muscle building, would deprive New York residents of the protections of the law. Balanced against Plaintiff and its members’ speculative fears of enforcement and conclusory allegations of economic harm, it would be against the public interest to grant the broad injunctive relief that Plaintiff seeks. *See Maryland v. King*, 567 U.S. 1301, *3 (2012) (Roberts, C.J., in chambers) (“[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury.” (citation omitted)).

CONCLUSION

Plaintiff’s motion for a preliminary injunction should be denied.

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Respectfully submitted,

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